

Remarks

This Amendment is in response to the Office Action dated **May 6, 2009**.

Claim Objections

Claim 66 has been objected to because of the following informalities: "Regarding claim 66, the claim should read "...said circumferential elastic bands are located... in order to maintain proper antecedent basis in the claims as written in other dependant claims such as 67."

Claim 66 has been amended.

Claim Rejections

35 U.S.C. §112

Claim 70 has been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. It is asserted in the Office Action that "[t]he specification and drawings do not support the first layer being the outer layer and the second layer being the inner layer with the area properties as claimed by Applicant." Office Action, p. 3.

Claim 32 from which claim 70 depends, does not specify if the first layer or the second layer is inner or outer. Rather, claim 32 recites the following:

An article comprising a multi-layer polymeric material film comprising at least first and second layers said first and second layers being in adherent contact with each other over a coextensive area along respective outer and inner surfaces, each of said first and second layers having an at-rest configuration defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface.

As the originally filed claims are part of the specification, claim 32 provides

support for either the first layer or the second layer being outer.

Applicants respectfully request withdrawal of the rejection of claim 70 under 35 U.S.C. §112, first paragraph.

35 U.S.C. §102(b)

Claims 27-28 and 63-64

Claims 27-28 and 63-64 have been rejected under 35 U.S.C. §102(b) as being anticipated by Boussignac et al. (USPN 5,000,734).

Applicants disagree.

It is asserted in the Office Action that “[r]egarding claims 27-28 and 63-64, Boussignac et al. disclose a medical balloon ... formed of radiation cured polymerized composition (col 3, ln 25-50) ...” Office Action, page 3.

This is incorrect.

Boussignac et al. disclose that:

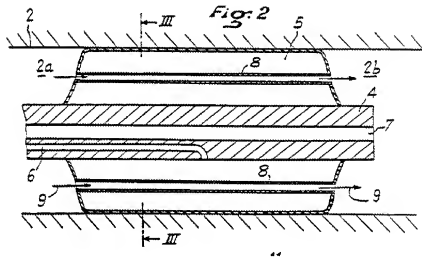
Structure 3 may be made of plastics material, such as polyvinyl chloride, a polytetrafluoroethylene, a polyethylene. It may, partly or completely, be constituted by a steel wire helically wound with contiguous turns and be externally or internally coated with polytetrafluoroethylene. Conduits 8 may also be made of plastics material. The bag element 5 will generally be made of supple plastics material, elastically deformable to allow its volume to be increased. It will be pre-shaped to the desired dimension and/or shape.

Structure 3 may be manufactured by the conventional processes of extrusion. The same may apply for the conduits 8 whilst the bag element 5 will generally be obtained by moulding. The conduits 8 and the bag element 5 may also be manufactured in one piece by moulding or by a process of manufacture of the same nature, this process of manufacture being desirable for reasons of safety. The uptakes of the exposure to rays may also be used to obtain the desired strengths and deformabilities. Column 3, lines 25-44.

It is unclear from this disclosure what the rays are and if they are actually be employed to form a cured polymerized composition at all. Furthermore, structure 3 appears to represent a catheter. The bag element 5 is attached to structure 3. It is also unclear if it is structure 3 that is exposed to the rays, or if any of the other elements are as well.

However, for purposes of expediting prosecution, independent claims 27 and 63 have been amended to recite, inter alia, in addition to the lumen that is offset from the balloon longitudinal axis, that a guidewire extends therethrough.

Fig. 2 of Boussignac et al. has been reproduced below to illustrate that it is lumen 7 that presents a passage for a guide means, and not any lumen that is offset from the longitudinal axis as recited in amended claims 27 and 63.



Rather, the canals or conduits disclosed by Boussignac et al. are for purposes of maintaining minimum circulation of fluid, and not for purposes of guiding.

According to the invention, this probe is characterized in that it comprises at least one conduit (8), connected to said structure (3), extending at least substantially parallel to said structure (3) and outside the latter, over a distance corresponding substantially to the longitudinal dimension of said bag element (5), so as to be able to place in communication those parts (2a, 2b) of said canal (2) immediately

upstream and downstream of said bag element (5) in order thus to maintain a minimum circulation of fluid in said canal (2).

Abstract

According to the invention, a plurality of conduits 8 (four in the example shown in FIG. 3) pass through the bag element 5, extending at least substantially parallel to the structure 3, in order to place in communication part 2a of the canal 2 immediately upstream of the bag element 5 and part 2b of the canal 2 immediately downstream of said bag element, thus ensuring minimum circulation of fluid (arrows 9) during the intervention (FIG. 2).

Column 2, lines 47-55

Claims 27 and 63 as amended, are not anticipated by Boussignac et al.

Claims 28 and 64 depend from claims 27 and 63 respectfully and are not anticipated by Boussignac et al. for at least these reasons.

Withdrawal of the rejection of claims 27-28 and 63-64 under 35 U.S.C. §102(b) as being anticipated by Boussignac et al. (USPN 5,000,734) is respectfully requested.

Claims 32-36

Claims 32-36 have been rejected under 35 U.S.C. §102(b) as being anticipated by Shaffer et al. (USPN 5,049,132).

Applicants traverse the rejection.

Claim 32 recites an article comprising a multi-layer polymeric material film comprising at least first and second layers, each layer having an inner and an outer surface, said *first and second layers being in adherent contact with each other over a coextensive area along respective outer and inner surfaces*, each of said first and second layers having an at-rest configuration defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface, the at-rest configuration being when said respective outer

and inner surfaces are unstressed.

It is asserted in the Office Action that:

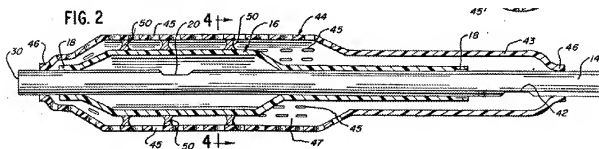
Regarding claims 32-36, Shaffer et al. discloses medical dilation balloon (4, Figure 1) comprising a multi-layer (44, 16) polymeric material film comprising at least first (44) and second layers (16), each layer having an inner and an outer surface, said first and second layers being in adherent contact (via posts 50) with each other over a coextensive area along respective outer and inner surfaces, each of said first and second layers having an at-rest configuration (deflated balloon state) defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface (in that the balloon layers (16, 44) are smaller and larger than one another respectively), the at-rest configuration being when said respective outer and inner surfaces are unstressed (i.e. deflated balloon state, Figures 1-4).

Office Action, page 4

Shaffer et al. clearly does not anticipate claim 32.

Claim 32 recites the first and second layers are in adherent contact with each other.

The layers 44 and 16 of the Shaffer et al. balloon, in contrast, each contact a post 50, but not each other. Fig. 2 of Shaffer et al. has been reproduced below to illustrate this.



As anticipation requires that all of the elements of the claim be disclosed in a single prior art reference and arranged as in the claim:

Because the hallmark of anticipation is prior invention, the prior art reference—in order to anticipate under 35 U.S.C. §102—must not only disclose all elements of the claim within the four corners of the document, but must also disclose those

elements “arranged as in the claim.” *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 [220 USPQ 193] (Fed. Cir. 1983).

The meaning of the expression “arranged as in the claim” is readily understood in relation to claims drawn to things such as ingredients mixed in some claimed order. In such instances, a reference that discloses all of the claimed ingredients, but not in the order claimed, would not anticipate, because the reference would be missing any disclosure of the limitations of the claimed invention “arranged as in the claim.” But the “arranged as in the claim” requirement is not limited to such a narrow set of “order of limitations” claims. Rather, our precedent informs that the “arranged as in the claim” requirement applies to all claims and refers to the need for an anticipatory reference to show all of the limitations of the claims arranged or combined in the same way as recited in the claims, not merely in a particular order. The test is thus more accurately understood to mean “arranged or combined in the same way as in the claim.” *Net MoneyIN Inc. v. VeriSign Inc.*, 88 USPQ2D 1751, 1758 (Fed. Cir. 2008).

Claim 32 is not anticipated by Shaffer et al.

Claims 33-36 depend from claim 32 and are not anticipated by Shaffer et al. for at least these reasons.

Withdrawal of the rejection of claims 32-36 under 35 U.S.C. §102(b) as being anticipated by Shaffer et al. (USPN 5,049,132) is respectfully requested.

35 U.S.C. §102(e)

Claims 32, 36-38, 65 and 69-70

Claims 32, 36-38, 65, and 69-70 have been rejected under 35 U.S.C. §102(e) as being anticipated by Steadham et al. (USPN7,331,933).

Applicants traverse the rejection with respect to claims 32, 36-38, 65 and 69-70.

Claim 32 recites an article comprising a multi-layer polymeric material film comprising at least first and second layers, each layer having an inner and an outer surface, said first and second layers being in adherent contact with each other over a coextensive area along

respective outer and inner surfaces, each of said first and second layers having an at-rest configuration defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface, the at-rest configuration being when said respective outer and inner surfaces are unstressed.

Applicants submit that Steadman et al. fail to disclose or suggest the area rest area of a first layer outer surface that is smaller than the at-rest area of a second layer inner surface wherein the inner and outer layers are in contact with each other.

It is asserted in the Office Action that:

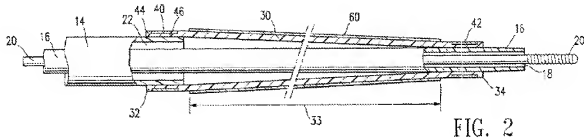
Regarding claims 32, 36-38, 65, and 69-70, Steadham et al. discloses medical dilation balloon (4, Figure 1) comprising a multi-layer (40, 30, 60, 42) polymeric material film comprising at least first (40) and second layers (30), each layer having an inner and an outer surface, said first and second layers being in adherent contact with each other over a coextensive area along respective outer and inner surfaces, each of said first and second layers having an at-rest configuration (deflated balloon state, unstretched band) defining an at-rest area on said respective outer and inner surfaces corresponding to said coextensive area, the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface (physical size differential between the layers, and pretensioned elastic bands that contract when placed upon the balloon) (col 4, ln 40-60) are smaller and larger than one another respectively), the at-rest configuration being when said respective outer and inner surfaces are unstressed (i.e. deflated balloon state, Figures 1-4).

Office Action, pp. 5-6

This is incorrect.

Applicants have reproduced Fig. 1 of Steadham et al. below in order to illustrate layers 40 and 30.

FIG. 1



The compression member referred to in the Office Action is represented by reference numeral 40. Balloon is represented by reference numeral 30.

Steadham et al. disclose, with respect to the compression members, the following:

In the embodiment illustrated in FIG. 1, a proximal compression member 40 and a distal compression member 42 sealingly secure the balloon 30 to the outer tubular member 14 and the inner tubular member 16, respectively. The compression members 40, 42 are bands with a first outer diameter that allow the bands to be placed around an outer surface of the balloon and which contracts to a second, smaller diameter which then secures the balloon 30 to the shaft 12. In one embodiment, compression members 40, 42 are radiopaque marker bands. FIGS. 1 and 2 also illustrates an outer diameter around the circumference the compression members 40, 42 which is not greater than the outer diameter of a first portion 44 of the skirt section 32 directly adjacent to a second portion 46 of the skirt section about which the compression member is mounted. However, in an alternative embodiment, the compression members 40, 42 may have an outer diameter, which is greater than the outer diameter of the directly adjacent portion of the balloon.

Column 4, lines 50-67

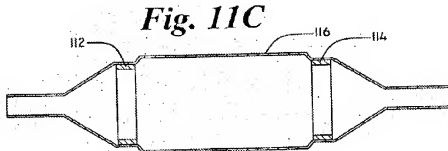
While Steadham et al. disclose that the outer diameter is not greater than the outer diameter of the first portion 44 of the balloon, they fail to disclose or suggest the at-rest area of said first layer outer surface being smaller than the at-rest area of said second layer inner surface, as recited in claim 32.

Anticipation requires that all elements of the claimed invention be disclosed in prior art reference. See *Net MoneyIN Inc. v. VeriSign Inc.*, 88 USPQ2D at 1758.

Claims 36-38 depend from claim 32 and are not anticipated by Steadham et al. for at least these reasons.

Independent claim 65 recites a balloon comprising a balloon body having a proximal end and a distal end, and the balloon comprising circumferential elastic bands on the proximal end or distal end of the balloon body, the elastic bands in their rest configuration have a smaller diameter than the balloon body in its at rest configuration.

Applicants have reproduced Fig. 11C below as an example of such an embodiment wherein elastic bands 112 and 114 are located on balloon body. See also paragraph [0101].



The Steadham et al. bands 40, 42, are located on the skirt sections of the balloon, not the body. Refer also to Fig. 1 reproduced above.

An inflatable balloon 30 is disposed on a distal section of catheter shaft 12. The balloon 30 has a proximal skirt 32 sealingly secured to the distal end of outer tubular member 14 and a distal skirt 34 sealingly secured to the distal end of inner tubular member 16. The balloon interior is in fluid communication with the annular inflation lumen 22. An adapter 36 at the proximal end of catheter shaft 12 is configured to provide access to the guidewire lumen 18 and to direct inflation fluid through arm 38 into the inflation lumen 22. The balloon 30 has an inflatable working length 33 located between the skirt sections 32, 34 of the balloon 30 and a stent 60 mounted on the balloon 30 for implanting in a patient's body lumen. FIG. 1 illustrates the balloon 30 in an uninflated configuration. The distal end of catheter 10 may be advanced to a desired region of a patient's body lumen in a conventional manner and the balloon 30 inflated.

In the embodiment illustrated in FIG. 1, a proximal compression member 40 and a distal compression member 42 sealingly secure the balloon 30 to the outer tubular

member 14 and the inner tubular member 16, respectively. The compression members 40, 42 are bands with a first outer diameter that allow the bands to be placed around an outer surface of the balloon and which contracts to a second, smaller diameter which then secures the balloon 30 to the shaft 12. In one embodiment, compression members 40, 42 are radiopaque marker bands. FIGS. 1 and 2 also illustrates an outer diameter around the circumference the compression members 40, 42 which is not greater than the outer diameter of a first portion 44 of the skirt section 32 directly adjacent to a second portion 46 of the skirt section about which the compression member is mounted. However, in an alternative embodiment, the compression members 40, 42 may have an outer diameter, which is greater than the outer diameter of the directly adjacent portion of the balloon.

Column 4, lines 22-49

Thus, claim 65 is also not anticipated by Steadham et al. because Steadham fails to disclose or suggest a balloon having elastic bands on the proximal and distal end of the body as recited in claim 65.

Claims 69-70 depend from claim 65 are also not anticipated by Steadham et al. for at least these reasons.

Withdrawal of the rejection of claims 32, 36-38, 65, and 69-70 under 35 U.S.C. §102(e) as being anticipated by Steadham et al. (USPN 7,331,933) is respectfully requested.

35 U.S.C. §103(a)

Claims 66-68

Claims 66-68 have been rejected under 35 U.S.C. §103(a) as being obvious over Steadham et al. (USPN 7,331 933) in view of Crocker et al. (USPN6,120,523). It is asserted in the Office Action that:

Steadham meets the claim limitations as described above except for the bands being located on in the interior of the balloon and the balloon comprising a radiation cured polymer composition.

However, Crocker et al. teaches a focalized intraluminal balloon.

Applicants traverse the rejection.

Claims 66-68 depend from claim 65.

Claim 65 has been discussed above.

Steadham et al. does not meet all of the claim limitations of independent claim 65 because Steadham fails to disclose or suggest a balloon having elastic bands on the proximal and distal end of the body as recited in claim 65.

Combining a focalized intraluminal balloon as disclosed by Crocker et al. still fails to render claim 65 obvious

Claims 66-68 are not obvious for at least these reasons.

Withdrawal of the rejection of claims 66-68 under 35 U.S.C. §103(a) as being obvious over Steadham et al. (USPN 7,331 933) in view of Crocker et al. (USPN6,120,523) is respectfully requested.

Claims 30-31

Claims 30 and 31 are rejected under 35 U.S.C 103(a) as being obvious over Boussignac et al. (USPN5,000,734). It is asserted in the Office Action that “Boussignac et al. meets the claim limitations as described above except for the device being used in with a stent delivery catheter or with a rapid exchange catheter.”

Applicants have amended claim 27 from which claims 30 and 31 depend.

Claim 27 as amended recites a medical balloon having a longitudinal axis and proximal and distal ends, the balloon formed of a radiation cured polymerizable composition, the balloon connecting to a coaxial shaft at the proximal end thereof and connecting to the same or a different coaxial shaft at the distal end thereof, and having a central body wall portion between

each end spaced apart from the balloon ends and connected thereto by means of tapering proximal and distal wall portions, respectively, wherein the balloon further comprises a lumen offset from the longitudinal axis, said lumen passing through the tapering proximal and distal wall portions of the balloon and a guidewire extending through said lumen.

Boussignac et al. fails to disclose or suggest a balloon having an offset lumen with a guidewire extending therethrough.

Claims 30 and 31 depend from claim 27 and are not obvious over Boussignac et al. for at least these reasons.

Withdrawal of the rejection of claims 30 and 31 is respectfully requested.

CONCLUSION

Claims 27, 28, 30-38 and 63-70 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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